UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AYLA PHARMA LLC,
Petitioner

v.

ALCON RESEARCH, LTD.,
Patent Owner.

U.S. Patent No. 9,533,053 to Gamache *et al.*
Case No.: IPR2020-00295

DECLARATION OF DR. S. CRAIG DYAR, PH.D., R.PH.

I, S. Craig Dyar, Ph.D., R.Ph., do hereby declare and state as follows:

1. I am over the age of eighteen (18) and otherwise competent to make this Declaration.

2. My name is S. Craig Dyar. I am currently President of SCD Pharma Consulting and a Senior Associate (Per Diem) at Lachman Consultants. I understand that my declaration is being submitted in connection with a Petition for *inter partes* review ("IPR") of United States Patent No. 9,533,053 ("the '053 Patent") (Exhibit 1002).

3. I am an expert in the field of developing and evaluating topical, ophthalmic, oral, transdermal, sublingual, rectal and sustained release dosage forms, and I have been an expert in this field since well before 2011, which I understand is the priority date of the '053 patent. A more complete recitation of my professional experience and qualifications may be found in my Curriculum Vitae (Exhibit 1043).

4. I have a Ph.D. in Pharmaceutical Sciences from the Medical University of South Carolina, Charleston; a B.S. Degree in Pharmacy from the Medical University of South Carolina, Charleston; and a B.S. Degree of Biology from the University of South Carolina.

5. I am currently, and have been since 2008, President of the SCD Pharma Consulting group and also have been since 2010 a Senior Associate (Pre-Diem) at Lachman Consultants. In this capacity, I have provided recommendations

to clients regarding the development of quality products beginning from discovery all the way to post-launch, life-cycle planning, intellectual property, project management, compound licensing and business development with a focus on drug delivery technologies related to dermal and ophthalmic ointments and other delivery technologies.

6. From 2008-2016, I was Assistant Professor at the School of Pharmacy of South University. During that time, I taught classes in pharmacokinetics and pharmaceutics, including ocular delivery methods and strategies, to graduate pharmacy students.

7. From 1998-2008, I was employed at Pfizer as a Scientist (1998-2000), Senior Scientist (2000-2001), Senior Principle Scientist (2001-2004) and Associate Research Fellow (2004-2008). During this time, I served on the Global Intellectual Property Board, the Global Drug Delivery Group, and managed several drug delivery projects related to immediate and sustained release oral tables, topical creams and ointments, sublingual tablets, transdermal formulations, targeted delivery systems (dendrimer and others), and orally dissolving tablets. I was also the lead on several pharmaceutical science teams directing numerous ophthalmology and dermatology projects. In particular from 2007-2008, I managed the NCE (New Chemical Entity) to phase 2 Ophthalmology portfolio, where I was responsible for the oversite of the chemistry, formulation and regulatory components of the programs.

8. From 1987-1994, I worked as a Registered Pharmacist where I was the

Pharmacist in Charge.

9. During my tenure, I have been an honorary member of Rho Chi Honor Society and American Association of Pharmaceutical Sciences and have been a Fellow of the American Foundation for Pharmaceutical Education (AFPE), and I have served as Chair of the AAPS year-round Task Force on Novel Drug Delivery Technology. In addition, I have published over 15 patents, patent applications, research publications, presentations, and/or posters and authored numerous Good manufacturing Practice/Good Laboratory Practice guidelines (GMP/GLP) and standard operating procedures (SOP).[1]

10. I have been retained in this matter by Ayla Pharma LLC ("Ayla") as a technical expert to provide analysis and opinions regarding the '053 patent. I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $350 per hour for consulting. My compensation does not depend in any way on the outcome of any of the IPR.

11. I understand that the '053 Patent is assigned to Alcon Research, LLC. ("Alcon," "Patentee," or "Patent Owner"). I have no personal or financial stake or interest in Petitioner, Patent Owner or the '053 Patent.

12. I understand that Dr. Paul Laskar previously submitted a combined

[1] I reserve the right to further explain my background and qualifications in deposition where needed.

declaration (EX1014) in connection with the '053 patent in *Cipla Ltd. v. Alcon Research Ltd.,* IPR2018-01021 and its related U.S. Patent No. 8,791,154 ("the '154 Patent") in *Cipla Ltd. v. Alcon Research Ltd.,* IPR2018-01020.

13. In the context of this retention, I have reviewed the Laskar declaration and its underlying materials. I agree with Dr. Laskar's reasons, findings and conclusions, and hereby adopt those reasons, findings and conclusions as if they were my own, including those with regard to those pertaining to the '053 patent as if I had signed the declaration myself with no changes to any opinions expressed therein.[2]

14. Although Dr. Laskar referred to the Abelson reference for his general statement of unpatentability of claims 1-13 under Grounds 1-3, I do note that Dr. Lasker only utilized Abelson as a prior art reference for claims 7 and 13. The remaining claims were shown unpatentable as obvious by Bhowmick in view of Yanni and Castillo under Ground 1, obvious by Schneider in view of Hayakawa, Bhowmick and Castillo under Ground 2, and obvious by Bhowmick, Schneider and Castillo under Ground 3. In this regard, I agree with Dr. Laskar's specific findings and conclusions on the obviousness of each challenged claim under Grounds 1-3.

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[2] In Dr. Lasker's Declaration paragraph 49, he shows the structure of Olopatadine and references the PDR. The structure is not shown in the PDR, but is well known and can be drawn from the chemical name in the PDR.

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